

Update on FDA's Regulatory Initiatives: Reproductive Tissues and Cells



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Implementation: 21 CFR Part 1271

3 Proposed Regulations

- ◆ May 1998, Establishment Registration and Product Listing
 - ◆ September 1999, Suitability Determination for Donors
 - ◆ January 2001, Current Good Tissue Practices (CGTP); Inspection and Enforcement
- Final Regulation – January 2001, Establishment Registration and Product Listing



Implementation of 21CFR Part 1271: Current Thinking

- ◆ **Publish Suitability Determination Final Rule – hold effective date**
- ◆ **Publish CGTP/Inspection and Compliance Final Rule**
- ◆ **Make both effective on the same date – 6 months**
- ◆ **Probability that effective date will be delayed – 1 year to January 2004**
 - ◆ **Provides longer period before effective**
 - ◆ **Allow establishments longer period to assure compliance**



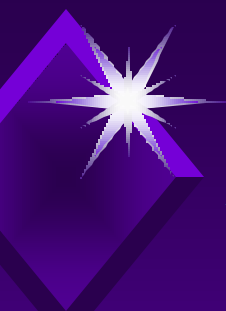
Implementation: Guidance

- ◆ Final Guidance – March 2002, Validation of Procedures for Processing of Human Tissues
- ◆ Draft Guidance – June 2002, Preventive Measures to Reduce the Possible Risk of Transmission of CJD/vCJD
- ◆ Draft Guidance – to be published, Suitability Determination for Donors of Human Cells, Tissue and Cellular and Tissue Based Products (HCT/Ps)



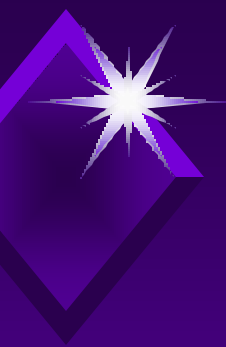
Registration and Listing

- ◆ Reproductive establishments can voluntarily register now – not currently subject to the regulations or FDA inspection
- ◆ Designated in the database at this time as “Not Required to Register”
- ◆ Estimated 400 ART clinics and 110 semen banks will register
- ◆ 505 establishments currently registered
 - ◆ 86 not required to register – stem/repro cells
- ◆ Piloting web-based system soon



Applicable Exemptions: 1271.15

- ◆ Establishments that only recover and immediately transfer tissue/cells into a sexually intimate partner of the donor
- ◆ Establishments that only receive/store HCT/Ps for use within their establishment
- ◆ Probably exempts most Ob/Gyn offices because of minimal risk concerns with
 - ◆ Communicable disease transmission
 - ◆ Contamination during processing



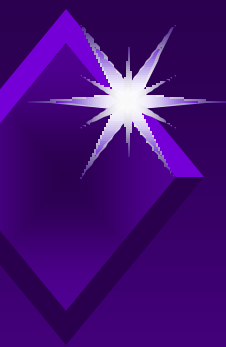
Recent Activities: FDA Letters

- ◆ July 2001 – Cells used in therapy involving transfer of genetic materials
- ◆ January 2002 – Lymphocyte immune therapy for recurrent miscarriage
- ◆ March 2002 – Cells or tissue intended for transplant that have ex-vivo contact with live nonhuman animal cells, tissue or organs
- ◆ FDA jurisdiction over clinical research/IND required



Other Recent FDA Activities

- ◆ December 2001, Advisory Committee: Risk factors for infectious disease transmission by artificial insemination
- ◆ May 2002, Advisory Committee: Ooplasm transfer as method to treat female infertility
- ◆ September 2002, FDA/NIH/DHHS Public Workshop on Evidence Based ART



Future Activities/Discussions

- ◆ FDA Workshop on Development of Donor Screening Assays for West Nile Virus - November 4/5, 2002, Bethesda MD
- ◆ Follow-up on identified issues from the November ART workshop
- ◆ Leveraging activities
 - ◆ ASRM development of CGTP guidance
 - ◆ Co-sponsoring public meetings



Information Available

- ◆ Website at www.fda.gov/cber/tiss.htm
 - ◆ Form 3356 – Registration/Listing
 - ◆ Published documents and letters
 - ◆ Meeting minutes/summaries/transcripts/presentations
- ◆ E-mail address for registration questions
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